

# **EXHIBIT 3**

**From:** Smith, Dan [ETHUS]  
**Sent:** Fri, 27 Feb 2004 15:53:53 GMT  
**To:** Burns, Janice [ETHGB] <JBURNS5@ethgb.jnj.com>  
**Subject:** RE: Important: 2 TVT Complaints concerning allegedly brittle mesh

**Importance:** High

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Janice,

I believe this MUST be discussed at a Ronnie, Alan, Laura, Barbara, Pryia level ASAP.

This is not new, and was exactly the original issue that stopped TVT blue for months. The fix (I'm not sure how complete) is to cut the mesh using ultrasonics, but it has not been validated and I'm not sure where it sits on the Operations priority list. I recall it was scheduled for mid to end of 2004 (last year) and Neuchatel will have to do this along with TVT Next, D'Art, the sheath splitting, and TVTO scale up.

I believe that the board has to set a directive that can be filtered down to the reps, saying its OK and its not an issue, same as TVT clear except you can see it. By the way you can also see it in the package as the pieces fall out of the sheath splits!

This is not going away anytime soon and competition will have a field day, major damage control offensive needs to start to educate the reps and surgeons UPFRONT that they will see BLUE shit and it is OK. This is why I wanted to launch TVTO in clear!!!!

PS remember as a fall back position, both Blue and Clear are validated for TVTO, we may have to do a small study at MediLine.

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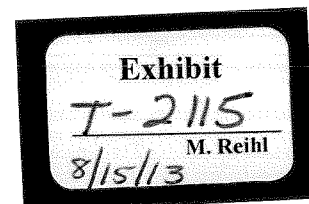
> -----Original Message-----

>From: Burns, Janice [ETHGB]  
>Sent: Friday, February 27, 2004 10:16 AM  
>To: Smith, Dan [ETHUS]  
>Subject: FW: Important: 2 TVT Complaints concerning allegedly brittle mesh  
>Importance: High

>  
>fyi  
>

> -----Original Message-----

>From: Fischer, Bernhard [MEDAT]  
>Sent: 27 February 2004 13:37



>To: Burns, Janice [ETHGB]  
>Subject: Important: 2 TVT Complaints concerning allegedly brittle mesh  
>Importance: High  
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>  
>Hello Janice,  
>  
>Dr. Mirna, who is one of the teachers in our TVT training centers here in Austria, today told us about 2 TVT complaints, both dealing with the same issue:  
>  
>- One complaint concerns TVT Retropubic Blue (LOT# 1120924)  
>- One complaint concerns TVT Obturator System (LOT# 1146532)  
>  
>  
>In both cases, the OR was carried out successfully without any complications. However, when cutting off the mesh above the skin incision and brushing the mesh with his fingers, Dr. Mirna noticed that small blue particles kept falling off the mesh, as if the mesh was as he put it "brittle".  
>  
>Since our mesh is now blue, would it be possible that this was always the case but now it is simply visible >as opposed to before the introduction of TVT Blue?  
>  
>He has provided us with the cut off mesh of both TVT Retropubic as well as TVT Obturator and I will send them in to Summerville.  
>However, as we are just in the phase of starting our trainings for TVT Obturator (with Dr. Mirna being among the teachers) and this is a crucial time for us, would it be possible to get feedback on this situation faster than with the usual reporting system (after sending complaints in, it usually takes over one month before receiving any feedback)?  
>  
>Could you please advise me what to do?  
>  
>Thanks a lot,  
>Bernhard  
>  
>  
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